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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,525	03/18/2002	Robert D. Simari	07039-280001	5964

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,525	SIMARI, ROBERT D.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-46 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 3, 4, 17-23 and 25-30, drawn to a method to inhibit or prevent heart failure in a mammal using a nucleic acid segment encoding a brain natriuretic peptide.

Group II, claim(s) 7, 8, 9, 10, 17-24, and 27-30, drawn to a method to inhibit or prevent heart failure in a mammal using a nucleic acid segment encoding a D-type natriuretic peptide.

Group III, claim(s) 3, 5, 17-23, and 25-30, drawn to a method to inhibit or prevent hypertension in a mammal using a nucleic acid segment encoding a brain natriuretic peptide.

Group IV, claim(s) 6, 9, 17-24, and 27-30, drawn to a method to inhibit or prevent hypertension in a mammal using a nucleic acid segment encoding a D-type natriuretic peptide.

Group V, claim(s) 3, 11, 17-23 and 25-30, drawn to a method to inhibit or prevent vasospasm in a mammal using a nucleic acid segment encoding a brain natriuretic peptide.

Group VI, claim(s) 9, 12, 17-24, and 27-30, drawn to a method to inhibit or prevent vasospasm in a mammal using a nucleic acid segment encoding a D-type natriuretic peptide.

Group VII, claim(s) 3, 13, 17-23, and 25-30, drawn to a method to inhibit or prevent atherosclerosis in a mammal using a nucleic acid segment encoding a brain natriuretic peptide.

Group VIII, claim(s) 9, 14, 17-24, and 27-30, drawn to a method to inhibit or prevent atherosclerosis in a mammal using a nucleic acid segment encoding a D-type natriuretic peptide.

Group IX, claim(s) 3, 15, 17-23, and 25-30, drawn to a method to inhibit or prevent vascular restenosis using a nucleic acid segment encoding a brain natriuretic peptide.

Group X, claim(s) 9, 16-24, and 27-30, drawn to a method to inhibit or prevent vascular restenosis using a nucleic acid segment encoding a D-type natriuretic peptide.

Group XI, claim(s) 31, 33, 35, 38, 39, 40, 41, 43, 44, 45, and 46, drawn to a viral vector comprising a nucleic acid molecule comprising a D-type natriuretic peptide.

Group XII, claim(s) 32, 34, 35, 36, 37, 38, 39, 40, 42, 44, 45, and 46, drawn to a viral vector comprising a nucleic acid molecule comprising a brain natriuretic peptide.

The inventions listed as Groups I-XII do not relate to a single invention concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the following reasons:

37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I is considered the main invention to the product first mentioned in the claims, and the first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

The technical feature linking groups I, III, V, VII, IX, and XII appear to be that they all relate to a nucleic acid encoding a brain natriuretic peptide or a method of increasing brain natriuretic peptide (BNP) levels in a mammal.

However, teaches LaPointe et al., (Hypertension, 27:715-722, 1996) teaches expressing the human BNP in rat hearts. Therefore, the technical feature linking the inventions of groups does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The nucleic acid molecule required in Groups I, III, V, VII, IX, and XII is not required in the Groups II, IV, VI, VIII, X, and XI.

In addition, in view of 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Groups II, IV, VI, VIII, X, and XI lack unity because the nucleic acid molecule comprising a D-type natriuretic peptide in Group XI can be used in several combinations as displayed in Groups II, IV, VI, VIII, and X.

The special technical feature of Group I is considered to be a method to inhibit or prevent heart failure in a mammal comprising a nucleic acid molecule comprising a brain natriuretic peptide.

The special technical feature of Group II is considered to be a method to inhibit or prevent heart failure in a mammal comprising a nucleic acid molecule comprising a D-type natriuretic peptide.

The special technical feature of Group III is considered to be a method to inhibit or prevent hypertension in a mammal comprising a nucleic acid molecule comprising a brain natriuretic peptide.

The special technical feature of Group IV is considered to be a method to inhibit or prevent hypertension in a mammal comprising a nucleic acid molecule comprising a D-type natriuretic peptide.

The special technical feature of Group V is considered to be a method to inhibit or prevent vasospasm in a mammal comprising a nucleic acid molecule comprising a brain natriuretic peptide.

The special technical feature of Group VI is considered to be a method to inhibit or prevent vasospasm in a mammal comprising a nucleic acid molecule comprising a D-type natriuretic peptide.

The special technical feature of Group VII is considered to be a method to inhibit or prevent atherosclerosis in a mammal comprising a nucleic acid molecule comprising a brain natriuretic peptide.

The special technical feature of Group VIII is considered to be a method to inhibit or prevent atherosclerosis in a mammal comprising a nucleic acid molecule comprising a D-type natriuretic peptide.

The special technical feature of Group IX is considered to be a method to inhibit or prevent vascular restenosis comprising a nucleic acid molecule comprising a brain natriuretic peptide.

The special technical feature of Group X is considered to be a method to inhibit or prevent vascular restenosis comprising a nucleic acid molecule comprising a D-type natriuretic peptide.

The special technical feature of Group XI is considered to be a viral vector comprising a nucleic acid molecule comprising a D-type natriuretic peptide.

The special technical feature of Group XII is considered to be a viral vector comprising a nucleic acid molecule comprising a brain natriuretic peptide.

Accordingly, Group I-XII are not so linked by the same or a corresponding technical feature as to form a single general inventive concept.

Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775.

The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE - Art Unit 1635, can be reached at (703) 306-3217.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER